

Remarks

This Request for Reconsideration is in response to the Office Action dated **August 12, 2009**. In the Office Action, the amendment to the specification was objected to; claims 27, 50, and 51 were rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement; claims 1-10, 13, 14, 48, 54, and 55 were rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of DiMatteo et al. (6,440,164); claim 11 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681), DiMatteo et al (6,440,164), and Rudakov et al. (6,451,050); claim 12 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681), DiMatteo et al. (6,440,164), Rudakov et al. (6,451,050), and Helmus et al. (2002/0032477); claims 22 and 26 were rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681), DiMatteo et al. (6,440,164), and Golds et al. (6,001,125); claims 19 and 20 were rejected under 35 USC 103(a) as being unpatentable over Houser at al. (6,149,681), DiMatteo et al. (6,440,164), and Rhodes (5,665,117); and claim 49 was rejected under 35 USC 103(a) as being unpatentable over Houser et al., (6,149,681), DiMatteo et al. (6,440,164), and Yang (2002/0062147).

The following comments are presented in the same order, with section headings, as the Office Action.

Specification

In the Office Action, the amendment to the specification was objected to under 35 USC 132(a) because it introduces new matter into the disclosure.

Specifically, the Office Action asserted that “the surface formed by liner 14 is a smooth surface while the surface formed by liner 16 is an uneven surface.” Applicant submits that Fig. 3 of the application as filed shows that liner 14 forms a smooth surface and that liner 16 forms an uneven surface:

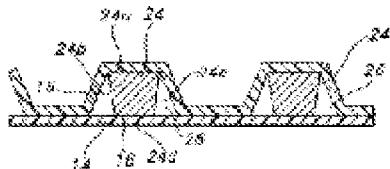


FIG. 3

Applicant notes that “smooth” and “uneven” are antonyms.¹ Smooth is defined as

1. free from projections or unevenness of surface; not rough²
2. generally flat or unruffled, as a calm sea³
3. Having a surface free from irregularities, roughness, or projections; even⁴
4. Having an even consistency⁵

and uneven is defined as:

1. not level or flat; rough; rugged⁶
2. irregular; varying; not uniform⁷
3. Not equal, as in size, length, or quality⁸
4. Not consistent or uniform⁹
5. Not smooth or level¹⁰
6. Not straight or parallel¹¹

As shown above in Fig. 3 of the application as filed, liner 14 clearly is not rough; is generally flat; has a surface free from irregularities, roughness or projections; and has an even consistency. As shown above in Fig. 3 of the application as filed, liner 16 clearly is not level or flat; is irregular, varying, and not uniform; is not equal, as in size, length, or quality; is not consistent or uniform; is not smooth or level; and is not straight or parallel. Therefore, Applicant

1 <http://thesaurus.reference.com/browse/smooth>, accessed October 6, 2009.

2 smooth. Dictionary.com. *Dictionary.com Unabridged*. Random House, Inc. <http://dictionary.reference.com/browse/smooth> (accessed: October 06, 2009).

3 *Id.*

4 smooth. Dictionary.com. *The American Heritage® Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Company, 2004. <http://dictionary.reference.com/browse/smooth> (accessed: October 06, 2009).

5 *Id.*

6 uneven. Dictionary.com. *Dictionary.com Unabridged*. Random House, Inc. <http://dictionary.reference.com/browse/uneven> (accessed: October 06, 2009).

7 *Id.*

8 uneven. Dictionary.com. *The American Heritage® Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Company, 2004. <http://dictionary.reference.com/browse/uneven> (accessed: October 06, 2009).

9 *Id.*

10 *Id.*

11 *Id.*

submits that the addition of “the surface formed by liner 14 is a smooth surface while the surface formed by liner 16 is an uneven surface” to the disclosure of the instant application is not new matter as it is supported by the original disclosure.

Moreover, in reference to the outer liner, the specification of the application as filed states:

The method of forming the composite intraluminal device ... may include laminating, adhering, or bonding the outer liner to the inner liner in a manner such that the ***outer liner substantially conforms to the complex geometry provided by the exterior surface and the openings of the stent***
Paragraph [0072], emphasis added

and in reference to the inner liner, the specification of the application as filed states:

In addition, as the inner luminal surface of the endoprosthesis is formed against a smooth mandrel in certain embodiment, the inner luminal surface of the composite endoprosthesis exhibits a relatively ***smooth*** configuration mitigating against turbulent blood flow and thrombosis formation during use.
Paragraph [0072], emphasis added

Whereas it is contemplated that liners 14 and 16 may be adhered at a location substantially coextensive with the interior surface 18 of the stent, it is further contemplated that the joining may occur at other locations. In those instances where the adherence occurs at a location coextensive with the interior surface 18 of the stent, this is especially beneficial for maintaining the ***smoothness*** of the inner luminal surface, so as to minimize the turbulence of or the interference with the fluid flowing through the device while also minimizing the risk of thrombosis formation.
Paragraph [0074], emphasis added

Applicant submits that the portions of the written specification provided above provide support for the addition of the recitation “the surface formed by liner 14 is a smooth surface while the surface formed by liner 16 is an uneven surface” to the specification.

Based on the above, the written description and the drawings as filed provide support for the recitation “the surface formed by liner 14 is a smooth surface while the surface formed by liner 16 is an uneven surface.” Therefore, the recitation is not new matter. Applicant requests withdrawal of the objection.

The Office Action further asserted that the addition of “[i]f the liners 14,16 are joined at a location between the interior surface 18 and the exterior surface 20, both surfaces 18,20 would be uneven. If the liners 14,16 are joined at a location that is coextensive with the

exterior surface 20 of the stent, the exterior surface 20 would be smooth and the interior surface 18 would be uneven” was not supported by the original disclosure.”

Applicant notes that paragraph [0033] of the original disclosure stated:

It is noted, however, that it is well within the contemplation of the present invention that the location at which liner 14 and liner 16 are joined may be at a location which is not coextensive with the interior surface of the stent.

Applicant submits that this provides support for liners joined between the interior surface and the exterior surface as well as for liner joined at a location coextensive with the exterior surface of the stent. As discussed above, the application as filed discloses that when the outer liner is joined to the inner liner at a location coextensive with the inner surface, the outer liner has an uneven surface. Thus, Applicant submits that one of ordinary skill would understand that if the opposite relationship were to occur, i.e. the inner liner joined to the outer liner at a location coextensive with the outer surface, that the inner liner would then have an uneven surface and the outer liner would have a smooth surface. Similarly, Applicant submits that one of ordinary skill understands that if the two liners are joined at a location between the interior surface and the exterior surface, both surfaces would be uneven. Therefore, Applicant submits that the recitation of “if the liners 14,16 are joined at a location between the interior surface 18 and the exterior surface 20, both surfaces 18,20 would be uneven. If the liners 14,16 are joined at a location that is coextensive with the exterior surface 20 of the stent, the exterior surface 20 would be smooth and the interior surface 18 would be uneven” was not supported by the original disclosure,” is not new matter since it is supported by the application as filed.

Based on the above, Applicant requests withdrawal of the objection to the amendment to the specification.

35 USC 112

In the Office Action, claims 27, 50, and 51 were rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed,

had possession of the claimed invention.

Specifically, the Office Action asserted that “[c]laim 27 contains the new matter cited in the amended specification filed 5/22/2009, as described above.”

Claim 27 recites in part “a first liner positioned about said inner surface of said tubular body, the first liner forming an inner surface of the device, the inner surface being smooth ... a second liner positioned about said outer surface of said tubular body, the second liner forming an outer surface of the device, the outer surface being uneven.”

As discussed above, Fig. 3 and the written specification of the application as filed provides support for the recitation of a first liner forming an inner surface that is smooth and a second liner forming an outer surface that is uneven. Therefore, Applicant submits that claim 27 complies with the written description requirement of 35 USC 112. Applicant requests withdrawal of the rejection.

Moreover, since claims 27, 50, and 51 were not rejected as being anticipated or obvious in view of any prior art, Applicant submits that claims 27, 50, and 51 are in condition for allowance.

35 USC 103 – Houser and DiMatteo

In the Office Action, claims 1-10, 13, 14, 48, 54, and 55 were rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of DiMatteo et al. (6,440,164).

Applicant notes that claims 54 and 55 were cancelled in the previous amendment.

Independent claim 1 recites in part “each pocket having a fluid containing a bioactive agent disposed therein, each pocket being pre-treated with a surfactant before the fluid is disposed therein.”

The Office Action does not assert that either Houser or DiMatteo disclose pre-treating the pocket with a surfactant as recited in claim 1 and Applicant was unable to find any disclosure in either Houser or DiMatteo regarding pre-treating a pocket with a surfactant.

For at least this reason, Applicant submits that the combination of Houser and DiMatteo does not teach or suggest each and every element of independent claim 1. Because

Houser and DiMatteo does not render claim 1 obvious, Applicant requests withdrawal of the rejection and submit that claim 1 and claims 2-10, 13, 14, and 48 dependent therefrom, are in condition for allowance.

35 USC 103 – Houser, DiMatteo, and Rudakov

In the Office Action, claim 11 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681), DiMatteo et al. (6,440,164), and Rudakov et al. (6,451,050).

Claim 11 depends upon independent claim 1. As discussed above, the combination of Houser and DiMatteo does not teach or suggest each and every element of independent claim 1. The Office Action asserted that “Rudakov et al. teaches a stent where the bioactive agent is encapsulated in a polymeric matrix.” Applicant submits that the asserted teaching of a bioactive agent encapsulated in a polymeric matrix by Rudakov does nothing to address the failure of Houser and DiMatteo to teach or suggest each and every element of independent claim 1. For at least this reason, Applicant submits that the combination of Houser, DiMatteo, and Rudakov does not render claim 11 obvious. Applicant requests withdrawal of the rejection and submits that claim 11 is in condition for allowance.

35 USC 103 – Houser, DiMatteo, Rudakov, and Helmus

In the Office Action, claim 12 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681), DiMatteo et al. (6,440,164), Rudakov et al., (6,451,050), and Helmus et al. (2002/0032477).

Claim 12 depends upon independent claim 11. As discussed above, the combination of Houser, DiMatteo and Rudakov does not teach or suggest each and every element of dependent claim 11. The Office Action asserted that “Helmus et al. teaches a biological prosthesis that uses microparticles in the matrix ... for the purpose of controlling the release of the bioactive agents.” Applicant submits that the asserted teaching of microparticles by Helmus does nothing to address the failure of Houser, DiMatteo, and Rudakov to teach or suggest each

and every element of claim 11. For at least this reason, Applicant submits that the combination of Houser, DiMatteo, Rudakov, and Helmus does not render claim 12 obvious. Applicant requests withdrawal of the rejection and submits that claim 12 is in condition for allowance.

35 USC 103 – Houser, DiMatteo, and Golds

In the Office Action, claims 22 and 26 were rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681), DiMatteo et al. (6,440,164), and Golds et al (6,001,125).

Claims 22 and 26 each depend on independent claim 1. As discussed above, the combination of Houser and DiMatteo does not teach or suggest each and every element of independent claim 1. The Office Action asserted that “Golds et al teaches a vascular graft constructed from porous ePTFE.” Applicants submit that the asserted teaching of a vascular graft constructed from porous ePTFE by Golds does nothing to address the failure of Houser and DiMatteo to teach or suggest each and every element of independent claim 1. For at least this reason, Applicant submits that the combination of Houser, DiMatteo, and Golds does not render claims 22 and 26 obvious.

Moreover, Applicant notes that Golds discloses using an inner tube having ePTFE with a higher IND (porous) for enhanced cell endothelization and an outer tube having ePTFE with a lower IND (non-porous) for strength (col. 3, lines 55-60; col. 4, lines 21-27). Thus, Golds does not disclose using porous ePTFE for both enhanced cell endothelization and greater strength.

35 USC 103 – Houser, DiMatteo, and Rhodes

In the Office Action, claim 19 and 20 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681), DiMatteo et al. (6,440,164), and Rhodes (5,665,117).

Claims 19 and 20 depend upon independent claim 1. As discussed above, the combination of Houser and DiMatteo does not teach or suggest each and every element of

independent claim 1. The Office Action asserted that “Rhodes teaches a biological prosthesis that uses stainless steel or tantalum to construct the device … for the purpose of utilizing the material’s biocompatibility.” Applicant submits that the asserted teaching of a prosthesis made from stainless steel or tantalum by Rhodes does nothing to address the failure of Houser and DiMatteo to teach or suggest each and every element of independent claim 1. For at least this reason, Applicant requests withdrawal of the rejection and submits that claims 19 and 20 are in condition for allowance.

35 USC 103 – Houser, DiMatteo, and Yang

In the Action, claim 49 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681), DiMatteo et al. (6,440,164), and Yang (2002/0062147).

Claim 49 depends upon independent claim 1. As discussed above, the combination of Houser and DiMatteo does not teach or suggest each and every element of independent claim 1. The Office Action asserted that “Yang teaches a biological prosthesis that uses a gel to contain the biological agent … for the purpose of retaining the drug in the device for a longer period of time.” Applicant submits that the asserted teaching of a gel by Yang does nothing to address the failure of Houser and DiMatteo to teach or suggest each and every element of independent claim 1. For at least this reason, Applicant requests withdrawal of the rejection and submits that claim 49 is in condition for allowance.

Conclusion

Based on at least the above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-14, 19-20, 22, 26-27, and 48-51 is requested.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

Date: October 22, 2009

By: / Jennifer L. Buss /
Jennifer L. Buss
Registration No.: 57321

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

f:\wpwork\jlb\14480us01_amd_20090820.doc